

DEC 19 2000

K003569

## **SECTION 9: 510(k) SUMMARY**

**Trade Name:** PlasmaKinetic™ Endourology Generator

**Submitter Name:** Gyrus Medical Limited,  
Fortran Road,  
St Mellons,  
Cardiff CF3 0LT,  
United Kingdom.

**Contact Person:** David Kay  
Director, Regulatory Affairs & Quality Assurance

Phone: [44] 2920 776300 Fax: [44] 2920 776304

**Date:** 17 November 2000

**Device Generic Name:** Electrosurgical Generator and Accessories

**Classification:** According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II.

**Product Code:** KNS (21 CFR 876.4300)

**Predicate Devices:** **Indications for Use** – K900628 – Gyrus Endourology  
Electrosurgical Generator  
**Technology Characteristics** - K003060 – Everest PlasmaKinetic™  
Electrosurgical Generator

**Product Description:**  
The device described in this 510(k) is an electrosurgical generator designed for use with bipolar electrosurgical instruments and accessories.

**Indications for Use:**  
The PlasmaKinetic™ Endourology Generator is an electrosurgical device intended for use in urological procedures involving the ablation or removal of soft tissue and where hemostasis is required. The specific urological indications where the device can be used are in transurethral prostatectomy (TURP) for benign prostatic hypertrophy, transurethral incision of the prostate (TUIP) or bladder neck, resection of bladder tumors and in cystodiathermy.

**Safety and Performance:**  
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled 'The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.' In support of this 510(k), Everest Medical has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Everest's subcontractor Design Control and Risk Analysis procedures and the results of validation testing (performance testing) for the device modification.

**Conclusion:**  
Based on the indications for use, technological characteristics and comparison to predicate devices the PlasmaKinetic™ Endourology Generator has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 19 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David Kay  
Regulatory Affairs and Quality Assurance Director  
Gyrus Medical Ltd  
Fortran Road, St. Mellons  
Cardiff CF3 0LT  
UNITED KINGDOM

Re: K003569  
PlasmaKinetic™ Endourology System  
Dated: November 17, 2000  
Received: November 20, 2000  
Regulatory Class: II  
21 CFR §876.4300/Procode: 78 KNS

Dear Mr. Kay:

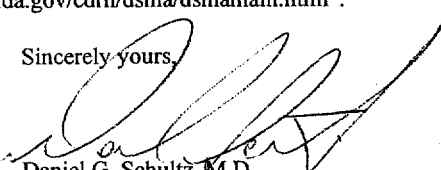
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003569

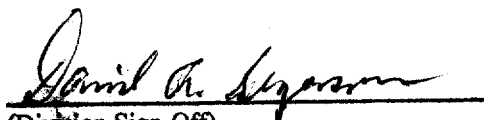
Device Name: PlasmaKinetic™ Endourology Generator

**Indications for use:**

The PlasmaKinetic™ Endourology Generator is an electrosurgical device intended for use in urological procedures involving the ablation or removal of soft tissue ~~and where hemostasis is~~ required. The specific urological indications where the device can be used are in transurethral prostatectomy (TURP) for benign prostatic hypertrophy, transurethral incision of the prostate (TUIP) or bladder neck, resection of bladder tumors and in cystodiathermy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K003569

Prescription Use N  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_